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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,227	01/08/2002	Bernd Riedl	BAYER 15(1)	5714
23599	7590	10/19/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,227	Applicant(s) RIEDL ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) 71-78 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3, 4,6-27, 33-37, 38-40, 42, 44, 45, 48-51, 53-55,58,59,61,62,64, 65, 67-70 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3,4,6-27,33-40,42,44,45,48-51,53-55,58,59,61,62,64,65 and 67-78.

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DETAILED ACTION

The request filed on 8/18/2004 for a Continued Examination Application (RCE) under 37 CFR 1.114 based on parent Application No. 09/889227 is acceptable and a RCE has been established. An action on the RCE follows.

Claims pending 1,3, 4,6-27, 33-37, 38-40, 42, 44, 45, 48-51, 53-55,58,59,61,62,64, 65,67-78.

Election /Restriction.

The applicants had elected group IV of the restriction in their response of Dec. 19 2002.

In response to the Restriction Requirement dated October 31, 2002, Applicant's hereby elect with traverse Group IV (claims 1-67 in part), drawn to compounds, pharmaceutical compositions and method of treating using compounds of Formula I, wherein A is L-M-L', wherein M is oxygen or sulphur, L is phenyl and L' is phenyl, pyridinyl or pyrimidinyl, and B is phenyl, substituted at least by a tert-butyl group or a trifluoromethyl group. Applicants traverse

Applicants have not amended the claims to the elected group.

The new claims 71-78 drawn to the formula I is either a duplicate claim or if the scope is different scope then it is drawn to another group XVI.

The 1449 filed 2/19/04 has been initialed and being sent herewith.

Applicants have amended the claims , however the rejections under 112 still stands. See below.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain hetero cyclic groups, does not reasonably provide enablement for any hetero ring from 1-3 atoms of N, O or S. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants can overcome this by putting in the specific hetero ring groups as given in the examples, such as the piperidine, piperazine, morpholine, pyrrole and pyridine.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites what is not, hence is not defining the claims in positive terms.

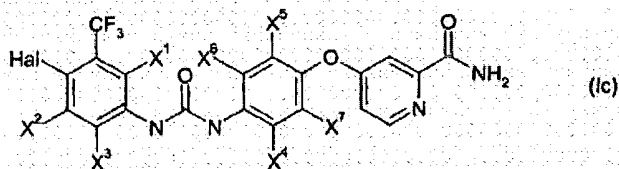
Double Patenting

Claims 1,3, 4,6-27, 33-37, 38-40, 42, 44, 45, 48-51, 53-55,58,59,61,62,64, 65, 67-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting

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as being unpatentable over claims 1-25 of the of copending Application No. 10/071248.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to a similar genus as given below.

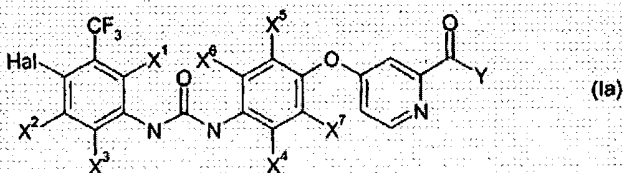


wherein,

Hal is chlorine or bromine, and

X¹ to X⁷ are each, independently, H, OH or -OC(O)C₁-C₄ alkyl,
or a salt or purified stereoisomer thereof.

and



wherein,

Y is NHR,

Hal is chlorine or bromine,

R is H, CH₃ or CH₂OH, and

X¹ to X⁷ are each, independently, H, OH or -OC(O)C₁-C₄ alkyl,
or a salt or purified stereoisomer thereof,

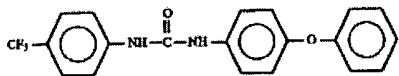
with the proviso that at least one of X¹ to X⁷ is OH or -OC(O)C₁-C₄ alkyl.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Close Art cited but not relied upon.

US 5710094 teaches compounds of the formula

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, wherein the L' is not substituted by C(O)Rx

The child applications of WO 9932436 and WO 9932463 have been abandoned.

Applicants have several US published applications, such as US 2003139605, US 2002042517, US 2003105091, US 2003139605, US 2002165394, US 2003068223, US 2003181442, US 2003207872, US 2004102636. Applicants should clearly indicate the clear line of demarcation of the claims since all are similar or provide a terminal disclaimer for the same.

Conclusion

The claims 1,3, 4,6-27, 33-37, 38-40, 42, 44, 45, 48-51, 53-55,58,59,61,62,64, 65, 67-70 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script, appearing to read "R. Desai", written over a horizontal line.

Rita J. Desai
Primary Examiner
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R.D.
October 8, 2004

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